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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,871	03/26/2001	Felix Frey	27656/37082	1259

7590

05/07/2003

Jeffrey S Sharp
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,871

Applicant(s)

FREY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-19 and 30 is/are rejected.
- 7) ☒ Claim(s) 15, 16 and 31 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

First Office Action on the Merits

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper Nos. 9 and 11 is acknowledged. The traversal is on the ground(s) that (a) the examiner has not shown that a serious burden would be required to examine the entire scope of claim 12 and (b) by requiring a single, specifically disclosed species from the elected Group, the patent office is impermissibly redrafting the claimed invention. This is not found persuasive because (a) the Markush group recited by claim 12 encompasses numerous different steroid compounds which apart from containing the steroidal moiety are structurally different and (b) the election of the a single, specifically disclosed species from under the elected Group, as stated in the previous Office Action, was for search purposes only.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's election, claims 20-29 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-14, 17-19 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Based on the use of the terms "steroid hormone" and "DNA-interacting molecule" and the definitions given by the present specification, the claimed invention encompasses a vast number of compounds. However, apart from the specific compounds recited by the present specification, the skilled artisan would be unable to make the claimed compounds because he would not know what other compounds fall within applicant's definition of the terms "steroid hormone" and "DNA-interacting

molecule". The skilled artisan would be unable to make and, therefore, use the claimed compounds commensurate in scope with the instant claims because the above-mentioned terms do not have a well-established meaning in the art. Therefore, he would first have to search and find compounds falling within the scope of applicant's definition before making and using the claimed compounds. The present specification lacks guidance to enable the skilled artisan to make other compounds as defined by the present invention. Because of the lack of guidance by the present specification and the state of the prior art, the skilled artisan would have to undertake undue experimentation in order to practice the claimed invention commensurate in scope with the instant claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-14, 17-19 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims creates confusion as to the claimed invention because of the recitation of the terms "steroid hormone" and "DNA-interacting molecule". The present specification discloses some compounds that are within the definition of the above-mentioned terms however, apart from the specific compounds set forth by the present specification, the skilled artisan would be unable to determine the metes and bound of the claimed invention. The skilled would be unable to

determine the metes and bound of the claimed invention because he would not know what other compounds are encompassed by the above-mentioned terms.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-8, 10-13, 17-19 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ponpipom et al.

Ponpipom et al. teach cell-specific ligands useful for the selective delivery of drugs to tissues and organs and method for making said ligands (see the entire article, especially page 1391, compound #23, **RN 79360-28-4**; page 1392, col. 1, paragraph 1; page 1394, col. 1, paragraph 5). The compounds and process of making taught by the reference are encompassed by the instant claims.

Allowable Subject Matter

9. Claims 15, 16 and 31 are objected to as being dependent upon a rejected base claim.

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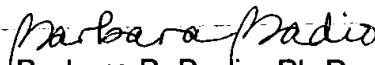
Note: The claims are allowable to the extent they read on the claimed compounds wherein (a) the glucocorticoid steroid hormone is dexamethasone, (b) the incorporating molecule is psoralen and (c) the spacer group comprises two urethane bonds.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


(Barbara P. Badio, Ph.D.)
Primary Examiner
Art Unit 1616

BB
May 1, 2003